

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

HOLOGIC, INC., and CYTYC SURGICAL
PRODUCTS, LLC,

Plaintiffs,

v.

MINERVA SURGICAL, INC.,

Defendant.

C.A. No.: 15-1031-JFB-SRF

REDACTED - PUBLIC VERSION

**PLAINTIFFS' RESPONSE TO MINERVA'S MOTION IN LIMINE NO. 1
TO EXCLUDE EVIDENCE OF WILLFULLNESS**

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July 2, 2018

Redacted Version: July 10, 2018

The Court should deny Minerva's Motion *in Limine* No. 1. (D.I. 383.)

First, Minerva seeks to exclude PTX-0041, a 2010 email from Minerva's Vice President of Regulatory and Clinical Affairs, Mary Edwards, with the subject line: "[REDACTED] [REDACTED]." (D.I. 293-2, Ex. 65). Ms. Edwards notes that [REDACTED] [REDACTED] [REDACTED]. (Id.) [REDACTED] [REDACTED] [REDACTED] [REDACTED] (Id. at 1 (emphasis added).) There is "no reason why a district court acting as a fact finder should ignore a party's representation to a federal regulatory body that is directly on point." *Intendis GMBH v. Glenmark Pharm. Inc.*, 822 F.3d 1355, 1362 (Fed. Cir. 2016). Minerva's cited authority is inapposite as it deals with statements made to the FDA to establish equivalence in a Premarket Notification (510(k)) or abbreviated new drug application (ANDA) — not [REDACTED] [REDACTED]. (D.I. 293-2, Ex. 65 at 1.) [REDACTED] [REDACTED]. (D.I. 383 at 1.) At a minimum, it is for the jury to decide whether it finds Minerva's explanation credible, especially where [REDACTED] [REDACTED]. (D.I. 325, Hol. Ex. 138 (Pollard Tr.) at 122:4-6, 123:2-4, 123:15-19, 124:18-125:4, 127:18-19, 129:17-21, 136:17-137:12, 137:21-138:6.)

Second,¹ Minerva seeks to exclude another of its bombshell admissions demonstrating it was aware of a substantial risk of infringement as early as 2011 when [REDACTED]

¹ Minerva's Motion comprises three motions *in limine*, exceeding the Court's limit of 6 motions *in limine*. (6/15/2018 Oral Order.)

[REDACTED]. (PTX-0058 (D.I. 293-4 at Ex. 83.) One of Minerva’s first 10 employees and Chief Operating Officer, Mike Regan, noted that [REDACTED]

[REDACTED]. (*Id.* at MSI00213689.) This “[REDACTED]” is a critical part of Minerva’s width indicator mechanism that infringes the ’348 Patent as a matter of law. (D.I. 407 at 34.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (PTX-0058 at MSI00213689.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.*) This communication is highly relevant to Minerva’s

[REDACTED]

[REDACTED] — all probative of the egregiousness of Minerva’s infringement. Minerva claims that Hologic [REDACTED]

[REDACTED]

[REDACTED]. (D.I. 383 at 2.) Minerva is wrong. The law

is clear that “[t]he testimony of a witness is not necessary to authenticate a document.” *Acorda Therapeutics Inc. v. Apotex Inc.*, No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *6 (D.N.J. Sept. 6, 2011), *aff’d*, 476 F. App’x 746 (Fed. Cir. 2012). Indeed, “[T]he burden of proof for authentication is slight.” *United States v. Reilly*, 33 F.3d 1396, 1404 (3d Cir. 1994). Unlike in *Rowe v. Conoco, Inc.*, No. 97-6107, 1998 U.S. App. LEXIS 13196, at *16-18 (10th Cir. June 19, 1998) and *Sullivan v. Warminster Twp.*, 461 F. App’x 157, 162 (3d Cir. 2012), several of

Minerva's own executives were recipients of the email chain. Minerva omits that [REDACTED]

[REDACTED] (Ex. 1 (4/21/2017 Clapper Depo Tr.) at 112:10-113:2.)² See Fed.

R. Evid. 801(d)(2), 803(1), 803(3), 803(5), 803(6), 807; 901(b)(1). Mr. Clapper will be a live witness at trial. Minerva also averred that [REDACTED]

[REDACTED]. (Ex. 2 at 1-2.) See Fed. R. Evid. 901(b)(4), 902(11), 902(12).) Dr. Skalny and Mr. Truckai, recipients of the email, will also be live witnesses at trial.

Third, Minerva seeks to exclude "any reference to lack of opinion of counsel" under 35 U.S.C § 298. But "[t]he protection granted by 35 U.S.C. § 298 dissolves in the event defendants 'open the door' by attempting to refute a claim of willful infringement by implying that they relied on the advice of counsel." *DSM IP Assets, B.V. v.ALLEMAND Specialties, Inc.*, No. 16-CV-497-WMC, 2018 WL 1937660, at *18 (W.D. Wis. Apr. 24, 2018). As noted above, Minerva

[REDACTED]. (PTX-0058 at MSI00213689.) Advice of counsel is not a shield and a sword. Minerva [REDACTED]

[REDACTED], but now wants to Hologic's ability to test the sufficiency and reasonableness of that advise, from which the Jury will determine the egregiousness of Minerva's conduct. Further, Minerva produced an opinion of counsel and has its opinion counsel, Mr. Burt Magen, on its witness list. Thus, it makes no sense to preclude Hologic from referencing a lack of opinion of counsel and Minerva's motion should be denied.

² Exhibits herein are attached to the accompanying Declaration of Ryan Casamiquela.

DATED: July 2, 2018

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on July 2, 2018, I caused to be electronically filed a true and correct copy of the foregoing sealed document with the Clerk of the Court using CM/ECF, and in addition caused true and correct copies of the foregoing sealed document to be served upon the following counsel of record by electronic mail:

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